

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| In re the Application of: DAVID RAAB ET AL. Serial No.: 10/539,208 Filed: May 24, 2006 For: METHOD AND DEVICE FOR OPTIMIZING A NUCLEOTIDE SEQUENCE FOR THE PURPOSE OF EXPRESSION OF A PROTEIN | Confirmation No. 2327 Art Unit: 1631 Examiner: ZHOU, Shubo |
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RESPONSE TO OFFICE ACTION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Office Action mailed on March 3, 2010, Applicants respectfully submit that their previous response, filed on 12/11/09, was indeed a proper response, as shown by the attached documents. In their response (copy attached), Applicants elected Group I, claims 1-16. The Restriction Requirement in the Office Action dated 11/12/2009 (copy attached) did not require a sequence election with respect to Group I. Accordingly, Applicants respectfully submit that the application is now in condition for examination on the merits.

Serial No.: 10/539,208
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Attorney's Docket No.: B&B-135-US
Page 2

PAUL, HASTINGS, JANOFKY & WALKER LLP
875 15th Street, N.W.
Washington, D.C. 20005
Tel: (202) 551-1700

Respectfully submitted,

DAVID RAAB ET AL

Date: March 30, 2010

By:

A handwritten signature in black ink, appearing to read 'Aslan Baghdadi', is written over a horizontal line.

Aslan Baghdadi
Registration No. 34,542

AB/hjm

Customer No. 36183

B&B-135-US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

DAVID RAAB ET AL.

Serial No.: 10/539,208

Filed: May 24, 2006

For: METHOD AND DEVICE FOR
OPTIMIZING A NUCLEOTIDE
SEQUENCE FOR THE PURPOSE
OF EXPRESSION OF A PROTEIN

Confirmation No. 2327

Art Unit: 1631

Examiner: ZHOU, Shubo

RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Office Action mailed on November 12, 2009, Applicants hereby elect to prosecute the claims of Group I (claims 1-16) in the present application.

PAUL, HASTINGS, JANOFKY & WALKER LLP
875 15th Street, N.W.
Washington, D.C. 20005
Tel: (202) 551-1700

Respectfully submitted,

DAVID RAAB ET AL.

Date: December 11, 2009

By:


Aslan Baghdadi

Registration No. 34,542

AB/

Customer No. 36183



UNITED STATES PATENT AND TRADEMARK OFFICE

1 Month

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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/539,208 | 05/24/2006 | David Raab | B&B-135 | 2327 |

909 7590 11/12/2009
PILLSBURY WINTHROP SHAW PITTMAN, LLP
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MCLEAN, VA 22102

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| EXAMINER |
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ZHOU, SHUBO

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| ART UNIT | PAPER NUMBER |
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1631

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| MAIL DATE | DELIVERY MODE |
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11/12/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|-------------------------------|-----------------------------|--|
| Office Action Summary | Application No. 10/539,208 | Applicant(s) RAAB ET AL. | |
| | Examiner SHUBO (Joe) ZHOU | Art Unit 1631 | |

- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-30 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-946) | Paper No(s)/Mail Date. ____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Restriction/Election Requirement

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- I. Claims 1-16, drawn to a method, device and computer program for optimizing a nucleotide sequence for the expression of a protein on the basis of the amino acid sequence of the protein, classified in Class 702, subclass 19.
- II. Claims 17-30, drawn to polynucleotides, vector and cell comprising the same, classified in Class 536, subclass 23.1 and 24.1. If this group is elected, the sequence election requirement set forth below is also applied.

The inventions of groups I-II are independent/distinct, each from the other because of the following reasons.

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, while the nucleic acid of group II can be made by a process of group I, it can also be made by ways of recombinant technology or chemical synthesis.

Sequence Election Requirement Applicable to Group II

In addition, the nucleic acids of group II reads on patentably distinct sequences. Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is

applied to Group II. Applicants must elect a single nucleic acid sequence (See MPEP 803.04). It is noted that the multitude of sequence submissions for examination has resulted in an undue search burden if more than one nucleic acid sequence is elected, thus making the previous waiver for up to 10 elected nucleic acid sequences effectively impossible to reasonably implement.

MPEP 803.04 states:

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions with the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Examination will be restricted to only the elected sequence.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 9 A.M. to 5 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran, can be reached on 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6

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am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/ Shubo Zhou/

Shubo (Joe) Zhou, Ph.D.
Primary Patent Examiner